

**WRITTEN OPINION OF THE
INTERNATIONAL PRELIMINARY SEARCHING
AUTHORITY (SEPARATE SHEET)**

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ANNEX 2
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International application Nr
PCT/FR2004/002330

Concerning point V

Reasoned statement pursuant to rule 66.2(a)(ii) with regard to novelty, inventive step and industrial application; citations and explanations supporting such statement

- 1 The present notification mentions the following documents, cited in the search report. The numbers given hereinafter shall be used in the rest of the procedure.

D1: WO 0107104

Novelty Article 33(2) PCT

- 2 The present application does not satisfy the requirements of article 33(1) PCT, since the subject matter of **claims 1 and 4** does not seem to comply with the novelty criterion as defined by article 33(2) PCT.

Document D1 describes a device for injection of a product (2) (figures 1-6), comprising:

- a body (1)
- a needle (4) and a container (ampule 3) able to move relative to the body
- means (support 5 and spring) for holding the needle in the injection position (figure 4), which means can be released to permit displacement of the needle to the retracted position (figure 6)
- means (actuating rod 14 of the activator element 12 and stop 19) for holding the container in the injection position (figure 4) to a retracted position (figure 6)
- a piston (17)
- first actuating means (unscrewing of the activator element 12) of means for holding the needle in position (support 5 and spring)
- second actuating means of said means holding the container in position (the second actuating means are identical to the first actuating means, i.e. to unscrewing of the activator element)
- said first and second actuating means making it possible, at the end of the injection, to respectively release the means for holding the needle in position before the release of the means for holding the container in position (figure 6)

- a container support (support 5 with stop 19) which is mounted slidably on the body and is displaceable relative to the latter in order to perform the injection (see figures 2 and 5), said container being connected to this support and being able to move relative to the latter between a position permitting injection (figure 5) and a retracted position (figure 6)
- means for holding (tongues 20) the container support (support 5), which means normally hold the container support in a standby position before the injection (figure 3)
- means actuating (Betätigungsglied : control means 16) the release of the means for holding (tongues 20) the container support permitting injection in position.

Inventive step Article 33(3) PCT

3. The arguments put forward in item 3 of the notification of 9 February 2005 are upheld and the present application does not satisfy the requirements of article 33(1) PCT, since the subject matter of **claims 2 and 3** does not seem to involve any inventive step as defined by article 33(3) PCT.

Concerning point VII

Some deficiencies in the international application

1. Contrary to the requirements of rule 5.1 a) ii) PCT, the description does not indicate the background art set out in document **D1** and does not cite that document.
2. The feature of the second actuating means being separate from the first appears to be new and inventive. This feature indeed allows for a limitation, in another way, of the freedom of action of the end user.
3. In order to satisfy the requirements of rule 5.1 a) ii) PCT, it is up to the applicant to justify his viewpoint by indicating, **in his new claim, in the characterizing part, the difference with regard to the prior art and to point to the benefits of the invention with regard to the state of the art.**

Concerning point VIII

Some remarks relating to the international application

Claim 1 is not supported by the description, as required in article 6 PCT, since its scope is broader than the scope which is justified by the description and drawings. According to the description and figures, the

first actuating means of the means for holding the needle in position are separate from the second actuating means of the means for holding the container in position.

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Concerning point V

Reasoned statement pursuant to rule 66.2(a)(ii) with regard to novelty, inventive step and industrial application; citations and explanations supporting such statement

- 1 The present notification mentions the following documents, cited in the search report. The numbers given hereinafter shall be used in the rest of the procedure.

D1: WO 0107104

D2: EP0516473

D3: US 2752918

Novelty Article 33(2) PCT

- 2 The present application does not satisfy the requirements of article 33(1) PCT, since the subject matter of **claims 1 and 4** does not seem to comply with the novelty criterion as defined by article 33(2) PCT.

Document D1 describes a device for injection of a product (2) (figures 1-6), comprising:

- a body (1)
- a needle (4) able to move relative to the body
- means (springs 15+7, body stop 13) for holding the needle in the injection position (figure 4), which means can be released to permit displacement of the needle to the retracted position (figure 6)
- means (springs 15+7, body stop 13) for holding the container in the injection position to a retracted position;
- a piston (17)
- respective means (16) actuating said means for holding in position
- a container support (5) which is mounted slidably with the body and container
- means for holding the container support in position (springs 7 and 15)
- actuating means (16)

Inventive step Article 33(3) PCT

3. The present application does not satisfy the requirements of article 33(1) PCT, since the subject matter of **claims 2 and 3** does not seem to involve any inventive step as defined by article 33(3) PCT.

Document D1, which is considered as the closest prior art, describes an injection device, and the device which forms the subject matter of claim 2 differs therefrom in that: - the means for holding the container support in position include a ring with a transverse tooth, a hook, an actuating spring which rests on the hook.

The problem the present invention intends to solve can therefore be considered as being the following: **how can the actions of the end user be otherwise limited to a maximum extent.**

Claim 2 describes a slight modification of the construction of the device described in claim 1; this modification belongs to common practice for the person skilled in the art, and the resulting advantages are easily predictable. Consequently, the subject matter of claims 2 and 3 does not involve any inventive step either.

Other comments

4. Contrary to the requirements of rule 5.1 a) ii) PCT, the description does not mention the relevant prior art disclosed in document **D1**, and does not cite this document.